DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
9 3144d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

March 7, 2002

Cory Alpert
Administrative Director – Clinical Services
Century City Hospital
2080 Century Park East; Suite #104
Los Angeles, CA 90067-2096

W/L Number: 27 - 02
Inspection ID: 2190140005
CFN: 20-30,334
FEI: 1000519450

Dear Mr. Alpert:

We are writing to you because on November 26, 2001, your facility was inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following REPEAT Level 2 finding at your facility:

- Level 2: The measured fog density is equal to 0.35 for mammography darkroom. This is a **REPEAT** violation.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as repeat Level 2 because it identifies a failure to meet a significant MQSA requirement in Title 21 Code of Federal Regulations section 900.12(e)(4)(i).

The background on this situation involves a trend of MQSA noncompliance. On November 20, 2000, your facility was inspected (Inspection ID number: 2190140004) with a partial finding of "***The measured fog density is equal to 0.23 in the mammography darkroom.***". On January 30, 2001, you wrote us a letter and stated "Lower watt bulbs have been ordered and installed for the Mammo darkroom. Also we

are using more filters over the light to maintain acceptable limits for the fog test. We will continue to use the lower watt bulbs, and keep the filters over the darkroom light.***". Based upon your willingness to correct this problem, we wrote your facility on February 15, 2001 that your voluntary corrective action was adequate, but subject to evaluation during your next regularly scheduled MQSA inspection. For your 2001 MQSA inspection, the same problem has been detected again only now at a higher level (0.35). As you should be aware, extraneous light and/or improper light bulbs, during developing of mammographic X-ray films, can decrease the quality of the mammogram presented to your radiologist(s) for medical interpretation.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction (DPC), charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Level 2: Medical audit and outcome analysis was not performed annually. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(1).

- Level 2: Medical audit and outcome analysis was not done separately for each individual. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(1).

- Level 2: Medical audit and outcome analysis was not done for the facility as a whole. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(1).

- Level 2: Phantom quality control (QC) records were missing for the weeks of November 20th through the 24th of the year 2000 plus February 12th through the 16th and February 26th through March 2nd of the year 2001 unit #3 (a [redacted] machine, model [redacted], serial number [redacted]) which is located in the mammography room. This is a violation of Title 21 Code of Federal Regulations section 900.12(e)(2).

- Level 2: The time period between the previous and current surveys for x-ray unit #3 (a [redacted] machine, model [redacted], serial number [redacted]) exceeds fourteen (14) months. This is a violation of Title 21 Code of Federal Regulations section 900.12(e)(9).

- Level 2: Not all positive mammograms were entered in the tracking system. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(1).

Your response should also include specifically why your proposed corrective action was not implemented or improperly implemented in January 2001. Who (by name and title) had the authority, capability, and responsibility to carryout that corrective action and why that individual did not. Finally, please submit not only your applicable revised quality assurance section(s) in reference to correcting this problem, but additionally your validation process to verify that the change procedure is, in fact, being carried out correctly this time.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- please provide sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; Suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general

information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (telephone number: 1-800-838-7715) or through the Internet at http://www.fda.gov

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Scott Goff (the Complianee Officer assigned to this case) at telephone number 949-798-7644.

Sincerely,

Alonza E. Cruse
District Director

cc:

State of California
Dept. of Health Services
Radiological Management Health Unit
3530 Wilshire Blvd.; 9th Floor
Los Angeles, CA 90010-2310